Species: RATS

**Toxicology Data Management System** 

Page: 4

Report Date: 05/18/2011

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Strain: F 344/N Length of Study: CHRONIC

#### **Study Summary**

Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical
					Male		
Battelle Columbus Laboratory	059903103	03/23/05	727	50(3)	38(706)	512.7	Ginkgo biloba extract
Battelle Columbus Laboratory	058810503	04/22/02	729	50(3)	35(702)	521.9	Isoeugenol
Battelle Columbus Laboratory	052000705	08/18/04	727	49(3)	34(692)	515.2	Kava kava extract
Battelle Columbus Laboratory	059902303	03/25/02	729	50(3)	29(683)	501.9	beta-Myrcene
Battelle Columbus Laboratory	052010703	10/20/04	727	50(3)	37(702)	503.5	N,N-Dimethyl-p-toluidine
Battelle Columbus Laboratory	059902005	04/09/03	727	50(3)	39(685)	514.9	Pulegone
					Female		
Battelle Columbus Laboratory	059903103	03/24/05	728	50(5)	37(700)	350.7	Ginkgo biloba extract
Battelle Columbus Laboratory	058810503	04/23/02	730	50(5)	33(699)	339.3	Isoeugenol
Battelle Columbus Laboratory	052000705	08/19/04	728	50(5)	34(683)	354.3	Kava kava extract
Battelle Columbus Laboratory	059902303	03/26/02	730	50(5)	31(668)	323.8	beta-Myrcene
Battelle Columbus Laboratory	052010703	10/21/04	728	50(5)	33(704)	354.1	N,N-Dimethyl-p-toluidine
Battelle Columbus Laboratory	059902005	04/10/03	728	50(5)	31(682)	341.2	Pulegone

Version: May2011 Contract/Lab: All Laboratories

Species: RATS

Strain: F 344/N

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Vehicle: CORN OIL

Page: 5

			Male				Female	
#All Organs: Benign Tumors								
-		50/50 (100%)	49/50 (98%)	49/49 (100%)		47/50 (94%)	41/50 (82%)	43/50 (86%)
		49/50 (98%)	48/50 (96%)	47/50 (94%)		40/50 (80%)	46/50 (92%)	42/50 (84%)
Overall Incidence	Total	292/299 (97.66%)	Mean 97.67%	SD 2.34%	Total	259/300 (86.33%)	Mean 86.33%	SD 5.57%
#All Organs: Malignant Tumors								
		13/50 (26%)	29/50 (58%)	17/49 (35%)		12/50 (24%)	18/50 (36%)	11/50 (22%)
	<b>.</b>	23/50 (46%)	20/50 (40%)	10/50 (20%)	<b>-</b>	11/50 (22%)	23/50 (46%)	8/50 (16%)
Overall Incidence	Total	112/299 (37.46%)	Mean 37.45%	SD 13.75%	Total	83/300 (27.67%)	Mean 27.67%	SD 11.13%
#All Organs: Malignant and Benign T	umors							
		50/50 (100%)	50/50 (100%)	49/49 (100%)		49/50 (98%)	46/50 (92%)	46/50 (92%)
		50/50 (100%)	49/50 (98%)	47/50 (94%)		45/50 (90%)	49/50 (98%)	44/50 (88%)
Overall Incidence	Total	295/299 (98.66%)	Mean 98.67%	SD 2.42%	Total	279/300 (93%)	Mean 93%	SD 4.15%
#All Organs: Hemangioma								
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/50 (2%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
#All Organs: Hemangiosarcoma								
-		0/50 (0%)	1/50 (2%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	2/50 (4%)
Overall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%	Total	2/300 (0.67%)	Mean 0.67%	SD 1.63%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Contract/Lab: All Laboratories

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

Page: 6

Report Date: 05/18/2011

Route: GAVAGE Vehicle: CORN OIL

Strain: F 344/N
Length of Study: CHRONIC

Male

			Male				Female	
#All Organs: Hemangiosarcoma or He	emangioma							
		0/50 (0%)	1/50 (2%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/50 (2%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	2/50 (4%)
Overall Incidence	Total	2/299 (0.67%)	Mean 0.67%	SD 1.03%	Total	3/300 (1%)	Mean 1%	SD 1.67%
#All Organs: Histiocytic Sarcoma								
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/300 (0%)	Mean 0%	SD 0%
#All Organs: Leukemia: Erythrocytic								
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#All Organs: Leukemia: Lymphocytic,	, Monocytic, M	lononuclear, or Undiffere						
		9/50 (18%)	10/50 (20%)	7/49 (14%)		8/50 (16%)	8/50 (16%)	5/50 (10%)
		9/50 (18%)	14/50 (28%)	4/50 (8%)		5/50 (10%)	15/50 (30%)	4/50 (8%)
Overall Incidence	Total	53/299 (17.73%)	Mean 17.71%	SD 6.59%	Total	45/300 (15%)	Mean 15%	SD 8.07%
#All Organs: Malignant Lymphoma: H	istiocytic, Lyn	nphocytic, Mixed, NOS, o	r Undifferentiated Cel	I Туре				
		0/50 (0%)	0/50 (0%)	1/49 (2%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1,00 (2,70)	0/00 (0/0)	(-,-,			` ,	

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Version: May2011 Contract/Lab: All Laboratories

Species: RATS

Strain: F 344/N

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Vehicle: CORN OIL

Page: 7

			Male				Female	
All Organs: Mesothelioma: Benign								
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
All Organs: Mesothelioma: Benign, M	lalignant, NOS	3						
		3/50 (6%)	3/50 (6%)	3/49 (6%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		2/50 (4%)	1/50 (2%)	2/50 (4%)		1/50 (2%)	0/50 (0%)	1/50 (2%)
verall Incidence	Total	14/299 (4.68%)	Mean 4.69%	SD 1.65%	Total	2/300 (0.67%)	Mean 0.67%	SD 1.03%
All Organs: Mesothelioma: Malignant		3/50 (6%)	3/50 (6%)	3/49 (6%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		2/50 (4%)	1/50 (2%)	2/50 (4%)		1/50 (2%)	0/50 (0%)	1/50 (2%)
verall Incidence	Total	14/299 (4.68%)	Mean 4.69%	SD 1.65%	Total	2/300 (0.67%)	Mean 0.67%	SD 1.03%
All Organs: Osteoma								
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
All Organs: Osteosarcoma								
		0/50 (0%)	2/50 (4%)	1/49 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	5/299 (1.67%)	Mean 1.67%	SD 1.51%	Total	0/300 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Version: May2011 Contract/Lab: All Laboratories

Species: RATS

Strain: F 344/N

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Page: 8 Report Date: 05/18/2011

			Male				Female	
#All Organs: Osteosarcoma or Osteoma	a							
		0/50 (0%)	2/50 (4%)	1/49 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	5/299 (1.67%)	Mean 1.67%	SD 1.51%	Total	0/300 (0%)	Mean 0%	SD 0%
Adrenal Cortex: Adenoma								
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	1/50 (2%)	2/50 (4%)		0/50 (0%)	3/50 (6%)	0/50 (0%)
verall Incidence	Total	4/299 (1.34%)	Mean 1.33%	SD 1.63%	Total	3/300 (1%)	Mean 1%	SD 2.45%
Adrenal Cortex: Carcinoma								
		0/50 (0%)	0/50 (0%)	1/49 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/299 (0.33%)	Mean 0.34%	SD 0.83%	Total	0/300 (0%)	Mean 0%	SD 0%
Adrenal Medulla: Ganglioneuroma								
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/300 (0%)	Mean 0%	SD 0%
Adrenal Medulla: Hemangioma								
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

GAVAGE

**Page**: 9

			Male				Female	
Adrenal Medulla: Pheochromocytoma Be	enign							
		11/50 (22%)	5/50 (10%)	5/49 (10%)		2/50 (4%)	2/50 (4%)	3/50 (6%)
Overall Incidence	Total	11/50 (22%) 46/299 (15.38%)	6/50 (12%) Mean 15.37%	8/50 (16%) SD 5.57%	Total	1/50 (2%) 13/300 (4.33%)	2/50 (4%) Mean 4.33%	3/50 (6%) SD 1.51%
		40/299 (13.3676)				13/300 (4.33 /6)		
*Adrenal Medulla: Pheochromocytoma Co	omplex							
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/300 (0%)	Mean 0%	SD 0%
*Adrenal Medulla: Pheochromocytoma M	alignant							
		2/50 (4%)	3/50 (6%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
O	T-1-1	2/50 (4%)	1/50 (2%)	0/50 (0%)	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	8/299 (2.68%)	Mean 2.67%	SD 2.42%	Total	0/300 (0%)	Mean 0%	SD 0%
*Adrenal Medulla: Pheochromocytoma: B	senign, Comple	x, Malignant, NOS						
-		12/50 (24%)	7/50 (14%)	5/49 (10%)		2/50 (4%)	2/50 (4%)	3/50 (6%)
		13/50 (26%)	8/50 (16%)	8/50 (16%)		1/50 (2%)	2/50 (4%)	3/50 (6%)
Overall Incidence	Total	53/299 (17.73%)	Mean 17.7%	SD 6.07%	Total	13/300 (4.33%)	Mean 4.33%	SD 1.51%
#Bone: Chordoma								
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/300 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

**Page:** 10

Mean 0%

SD 0%

Report Date: 05/18/2011

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC Male **Female** #Bone: Osteoma 0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%) 0/50 (0%)0/50 (0%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/300 (0%) **Overall Incidence** Total 0/299 (0%) Mean 0% SD 0% Total Mean 0% SD 0% #Bone: Osteosarcoma (0%)(0%)0/50 2/50 (4%)1/49 (2%)0/50 0/50 (0%)0/50 (0%)1/50 (2%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)Mean 1.67% Mean 0% **Overall Incidence** Total 5/299 (1.67%) SD 1.51% Total 0/300 (0%) SD 0% #Bone: Osteosarcoma or Osteoma 0/50 (0%)2/50 (4%)1/49 (2%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 5/299 (1.67%) Mean 1.67% SD 1.51% 0/300 (0%) Mean 0% SD 0% Total \*Brain: **Astrocytoma Malignant** 0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/299 (0.33%) Mean 0.33% SD 0.82% Total 0/300 (0%) Mean 0% SD 0% \*Brain: **Ependymoma Benign** 0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)

SD 0.82%

Total

0/300 (0%)

Total

1/299 (0.33%)

.....

Mean 0.33%

**Overall Incidence** 

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

rted Control Animal Groups

Report Date: 05/18/2011

GAVAGE

CORN OIL

Page: 11

			Male				Female	
Brain: Ependymoma Malignant								
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Brain: Glioma								
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
*Brain: Glioma Benign								
_		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Brain: Glioma Malignant								
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Brain: Granular Cell Tumor Benign								
_		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

**Page:** 12

Report Date: 05/18/2011

Route: GAVAGE Vehicle: CORN OIL

Contract/Lab: All Laboratories

Strain: F 344/N Length of Study: CHRONIC

			Male				Female	
Brain: Oligodendroglioma Benign	ı							
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/300 (0%)	Mean 0%	SD 0%
Brain: Oligodendroglioma Maligna	ant							
		0/50 (0%)	1/50 (2%)	0/49 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
Oligodendroglioma, Glioma	Total	0/50 (0%) 1/50 (2%) 3/299 (1%)	1/50 (2%) 0/50 (0%) Mean 1%	0/49 (0%) 1/50 (2%) SD 1.1%	Total	0/50 (0%) 0/50 (0%) 1/300 (0.33%)	1/50 (2%) 0/50 (0%) Mean 0.33%	0/50 (0%) 0/50 (0%) SD 0.82%
*Brain: Osteosarcoma		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
*Brain: Schwannoma Malignant								
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** \*Clitoral/Preputial Gland: Adenoma 4/50 (8%)2/50 (4%)0/49 (0%)5/50 (10%)3/48 (6%)2/50 (4%)(10%)5/50 (10%)0/50 (0%)3/50 (6%)(14%)5/50 3/50 (6%)14/299 (4.68%) 25/298 (8.39%) **Overall Incidence** Total Mean 4.67% SD 4.13% Total Mean 8.38% SD 3.64% \*Clitoral/Preputial Gland: Carcinoma (0%)(0%)0/50 2/50 (4%)1/49 (2%)0/50 2/48 (4%)2/50 (4%)(0%) 0/50 0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)Mean 1.34% **Overall Incidence** Total 4/299 (1.34%) SD 1.64% Total 4/298 (1.34%) Mean 1.36% SD 2.11% \*Clitoral/Preputial Gland: Carcinoma or Adenoma 4/50 (8%)4/50 (8%)1/49 (2%)5/50 (10%)5/48 (10%)4/50 (8%)5/50 (10%)0/50 (0%)4/50 (8%)7/50 (14%)5/50 (10%)3/50 (6%)**Overall Incidence** Total 18/299 (6.02%) Mean 6.01% SD 3.99% 29/298 (9.73%) Mean 9.74% SD 2.67% Total \*Clitoral/Preputial Gland: Sarcoma 0/50 0/49 (0%)0/50 (0%)(0%)0/50 (0%)0/48 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/299 (0%) Mean 0% SD 0% Total 0/298 (0%) Mean 0% SD 0% #Ear: **Neural Crest Tumor** 0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)

SD 0%

Total

2/300 (0.67%)

Total

0/299 (0%)

Mean 0%

**Overall Incidence** 

**Page:** 13

Mean 0.67%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

**Toxicology Data Management System** 

Page: 14

Report Date: 05/18/2011

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

			Male		Female
#Esophagus: Lipoma					
		0/50 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/50 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%	0/50 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%
	Total	0/299 (0%)	Mean 0% SD 0%	Total 0/300 (0%)	Mean 0% SD 0%
#Eye: Melanoma Benign					
		0/50 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)
Occupation of days as	T-1-1	0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%) 0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0% SD 0%	Total 1/300 (0.33%)	Mean 0.33% SD 0.82%
#Eye: Melanoma Malignant					
		0/50 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0% SD 0%	Total 0/300 (0%)	Mean 0% SD 0%
#Eye: Schwannoma Malignant					
		0/50 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0% SD 0%	Total 0/300 (0%)	Mean 0% SD 0%
#Harderian Gland: Adenoma					
		0/50 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0% SD 0%	Total 0/300 (0%)	Mean 0% SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

**Toxicology Data Management System** 

**Page:** 15

Report Date: 05/18/2011

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

			Male				Female	
#Harderian Gland: Carcinoma								
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Harderian Gland: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
*Heart: Schwannoma Benign								
_		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
Heart: Schwannoma Malignant								
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Intestine Large: Colon/Rec								
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Version: May2011 Contract/Lab: All Laboratories

Species: RATS

Strain: F 344/N

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Vehicle: CORN OIL

**Page:** 16

			Male				Female	
#Intestine Large: Colon/Red Carcinoma or Adenoma	ctum:							
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Intestine Large: Colon/Red Hemangioma								
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Intestine Small: Duodenun Carcinoma								
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Intestine Small: Duodenun Leiomyoma	n:							
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Intestine Small: Duodenun Schwannoma Malignant	n:							
•		0/50 (0%)	0/50 (0%)	0/49 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

**Toxicology Data Management System** 

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 17

Report Date: 05/18/2011

Length of Study: CHRONIC

Male **Female** #Intestine Small: Ileum: Adenoma 0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/300 (0%) **Overall Incidence** Total 0/299 (0%) Mean 0% SD 0% Total Mean 0% SD 0% #Intestine Small: Jejunum: Carcinoma 0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/299 (0%) Mean 0% SD 0% Total 0/300 (0%) Mean 0% SD 0% #Intestine Small: Jejunum: **Granular Cell Tumor Malignant** 0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/299 (0%) Mean 0% SD 0% Total 0/300 (0%) Mean 0% SD 0% #Intestine Small: Jejunum: Leiomyoma 0/49 1/50 (2%)1/50 (2%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 2/299 (0.67%) Mean 0.67% SD 1.03% Total 0/300 (0%) Mean 0% SD 0% #Intestine Small: Jejunum: Leiomyosarcoma 0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)**Overall Incidence** Total 0/299 (0%) Mean 0% SD 0% Total 1/300 (0.33%) Mean 0.33% SD 0.82% ......

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

**Page:** 18

Report Date: 05/18/2011

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

			Male				Female	
#Intestine Small: Site Un Adenoma	specified:							
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
	<b>-</b>	0/50 (0%)	0/50 (0%)	0/50 (0%)	<b>+</b>	0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Intestine Small: Site Un Carcinoma	specified:							
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Intestine Small: Site Un Carcinoma or Adenom								
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
	<b>-</b>	0/50 (0%)	0/50 (0%)	0/50 (0%)	<b>+</b>	0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Intestine Small: Site Un Granular Cell Tumor N	•							
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Intestine Small: Site Un Leiomyoma	specified:							
		1/50 (2%)	1/50 (2%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/299 (0.67%)	Mean 0.67%	SD 1.03%	Total	0/300 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

**Page:** 19

Report Date: 05/18/2011

Contract/Lab: All Laboratories

Species: RATS
Strain: F 344/N

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC Male **Female** #Intestine Small: Site Unspecified: Leiomyosarcoma 0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)1/300 (0.33%) **Overall Incidence** Total 0/299 (0%) Mean 0% SD 0% Total Mean 0.33% SD 0.82% #Intestine Small: Site Unspecified: Schwannoma Malignant (0%)(2%)0/50 0/50 (0%)0/49 (0%)1/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/299 (0%) Mean 0% SD 0% Total 1/300 (0.33%) Mean 0.33% SD 0.82% ...... \*Islets, Pancreatic: Adenoma 4/50 (8%)4/50 (8%)4/49 (8%)1/50 (2%)0/50 (0%)1/50 (2%)2/50 (4%)2/50 (4%)2/50 (4%)1/50 (2%)0/50 (0%)1/50 (2%)**Overall Incidence** Total 18/299 (6.02%) Mean 6.03% SD 2.22% 4/300 (1.33%) Mean 1.33% SD 1.03% Total \*Islets, Pancreatic: Carcinoma 0/49 0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 2/299 (0.67%) Mean 0.67% SD 1.03% Total 0/300 (0%) Mean 0% SD 0% \*Islets, Pancreatic: Carcinoma or Adenoma 4/50 (8%)4/50 (8%)4/49 (8%)1/50 0/50 (0%)1/50 (2%)

2/50

SD 1.66%

(4%)

1/50

4/300 (1.33%)

Total

(2%)

0/50

(0%)

Mean 1.33%

1/50

(2%)

Total

3/50

20/299 (6.69%)

(6%)

3/50

Mean 6.69%

(6%)

**Overall Incidence** 

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Report Date: 05/18/2011

**Page:** 20

			Male				Female	
Kidney: Pelvis and Tran Carcinoma	sitional Epitheli	um:						
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/300 (0%)	Mean 0%	SD 0%
Kidney: Pelvis and Tran Carcinoma or Adenom		um:						
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/300 (0%)	Mean 0%	SD 0%
Kidney: Pelvis and Tran Papilloma	sitional Epitheli	um:						
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
	<b>-</b>	0/50 (0%)	0/50 (0%)	0/50 (0%)	<b>-</b>	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Kidney: Renal Tubule: Adenoma								
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/50 (2%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/299 (0.67%)	Mean 0.67%	SD 1.03%	Total	0/300 (0%)	Mean 0%	SD 0%
Kidney: Renal Tubule: Carcinoma								
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Version: May2011 Contract/Lab: All Laboratories

Species: RATS

Strain: F 344/N

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Vehicle: CORN OIL

**Page:** 21

			Male				Female	
Kidney: Renal Tubule: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/50 (2%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/299 (0.67%)	Mean 0.67%	SD 1.03%	Total	0/300 (0%)	Mean 0%	SD 0%
Kidney: Renal Tubule: Hemangiosarcoma								
		0/50 (0%)	1/50 (2%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/300 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Lipoma								
•		1/50 (2%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/299 (0.67%)	Mean 0.67%	SD 1.03%	Total	0/300 (0%)	Mean 0%	SD 0%
'Kidney: Renal Tubule: Mesenchymal Tumor Beni	gn							
•	_	0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Kidney: Renal Tubule:  Mesenchymal Tumor Malig	gnant							
,	-	0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: CORN OIL

**Page:** 22

			Male				Female	
*Kidney: Renal Tubule: Nephroblastoma								
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
*Kidney: Renal Tubule: Sarcoma								
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
*Liver: Cholangioma								
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
*Liver: Hemangiosarcoma								
-		0/50 (0%)	1/50 (2%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/300 (0%)	Mean 0%	SD 0%
Liver: Hepatocellular Adenoma								
-		0/50 (0%)	1/50 (2%)	1/49 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	3/299 (1%)	Mean 1.01%	SD 1.1%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

**Page:** 23

Report Date: 05/18/2011

Route: GAVAGE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: CORN OIL

			Male				Female	
Liver: Hepatocellular Carcinon	na							
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Liver: Hepatocellular Carcinon								
·	•	0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
	Tatal	0/50 (0%) 0/50 (0%) 3/299 (1%)	1/50 (2%) 0/50 (0%) Mean 1.01%	1/49 (2%) 1/50 (2%) SD 1.1%	Total	0/50 (0%) 0/50 (0%) 1/300 (0.33%)	0/50 (0%) 0/50 (0%) Mean 0.33%	0/50 (0%) 1/50 (2%) SD 0.82%
Overall Incidence	Total	3/299 (170)						
			olastoma					
Liver:		lar Adenoma, or Hepatol	1/50 (2%)	1/49 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Liver:		lar Adenoma, or Hepatol		1/49 (2%) 1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)
Liver: Hepatocellular Carcinon		lar Adenoma, or Hepatol	1/50 (2%)	` ,	Total	` '	` ,	` ,
Liver: Hepatocellular Carcinon Overall Incidence	na, Hepatocellu	lar Adenoma, or Hepatol 0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	1/50 (2%)	Total	0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence * Liver:	na, Hepatocellu	lar Adenoma, or Hepatol 0/50 (0%) 0/50 (0%) 3/299 (1%) 0/50 (0%)	1/50 (2%) 0/50 (0%) Mean 1.01% 	1/50 (2%) SD 1.1% 0/49 (0%)	Total	0/50 (0%) 1/300 (0.33%) 0/50 (0%)	0/50 (0%) Mean 0.33% 	1/50 (2%) SD 0.82% 0/50 (0%)
'Liver:  Hepatocellular Carcinon  Overall Incidence  'Liver:	na, Hepatocellu	lar Adenoma, or Hepatol 0/50 (0%) 0/50 (0%) 3/299 (1%)	1/50 (2%) 0/50 (0%) Mean 1.01%	1/50 (2%) SD 1.1%	Total	0/50 (0%) 1/300 (0.33%)	0/50 (0%) Mean 0.33%	1/50 (2%) SD 0.82%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: CORN OIL

Page: 24

			Male				Female	
Lung: Alveolar/Bronchiolar A	denoma							
		1/50 (2%)	3/50 (6%)	2/49 (4%)		4/50 (8%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	3/50 (6%) 9/299 (3.01%)	0/50 (0%) Mean 3.01%	0/50 (0%) SD 2.76%	Total	4/50 (8%) 12/300 (4%)	1/50 (2%) Mean 4%	2/50 (4%) SD 3.35%
Lung: Alveolar/Bronchiolar C								
		0/50 (0%)	1/50 (2%)	1/49 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	3/299 (1%)	Mean 1.01%	SD 1.1%	Total	0/300 (0%)	Mean 0%	SD 0%
Alveolar/Bronchiolar C	arcinoma or Alv	veolar/Bronchiolar Aden		2/40 (40/)		A/FO (90/)	4/50 (20/)	0/50 (00/)
	arcinoma or Alv Total	veolar/Bronchiolar Aden 1/50 (2%) 3/50 (6%) 11/299 (3.68%)	4/50 (8%) 0/50 (0%) Mean 3.68%	2/49 (4%) 1/50 (2%) SD 2.95%	Total	4/50 (8%) 4/50 (8%) 12/300 (4%)	1/50 (2%) 1/50 (2%) Mean 4%	0/50 (0%) 2/50 (4%) SD 3.35%
Overall Incidence 		1/50 (2%) 3/50 (6%)	4/50 (8%) 0/50 (0%) Mean 3.68%	1/50 (2%)		4/50 (8%) 12/300 (4%)	1/50 (2%)	2/50 (4%)
Overall Incidence		1/50 (2%) 3/50 (6%)	4/50 (8%) 0/50 (0%) Mean 3.68%	1/50 (2%) SD 2.95%		4/50 (8%) 12/300 (4%)	1/50 (2%)	2/50 (4%)
Overall Incidence Lung:		1/50 (2%) 3/50 (6%) 11/299 (3.68%)	4/50 (8%) 0/50 (0%) Mean 3.68%	1/50 (2%) SD 2.95%		4/50 (8%) 12/300 (4%)	1/50 (2%) Mean 4%	2/50 (4%) SD 3.35%
Overall Incidence 'Lung: Fibrosarcoma		1/50 (2%) 3/50 (6%) 11/299 (3.68%) 0/50 (0%)	4/50 (8%) 0/50 (0%) Mean 3.68%	1/50 (2%) SD 2.95% 0/49 (0%)		4/50 (8%) 12/300 (4%) 0/50 (0%)	1/50 (2%) Mean 4% 0/50 (0%)	2/50 (4%) SD 3.35% 1/50 (2%)
Overall Incidence *Lung: Fibrosarcoma Overall Incidence	Total	1/50 (2%) 3/50 (6%) 11/299 (3.68%) 0/50 (0%) 0/50 (0%)	4/50 (8%) 0/50 (0%) Mean 3.68% 0/50 (0%) 0/50 (0%)	1/50 (2%) SD 2.95% 0/49 (0%) 0/50 (0%)		4/50 (8%) 12/300 (4%) 0/50 (0%) 0/50 (0%)	1/50 (2%) Mean 4% 0/50 (0%) 0/50 (0%)	2/50 (4%) SD 3.35% 1/50 (2%) 0/50 (0%)
Overall Incidence  *Lung: Fibrosarcoma  Overall Incidence  *Lung:	Total	1/50 (2%) 3/50 (6%) 11/299 (3.68%) 0/50 (0%) 0/50 (0%) 0/299 (0%)	4/50 (8%) 0/50 (0%) Mean 3.68% 0/50 (0%) 0/50 (0%) Mean 0%	1/50 (2%) SD 2.95%  0/49 (0%) 0/50 (0%) SD 0%		4/50 (8%) 12/300 (4%) 0/50 (0%) 0/50 (0%) 1/300 (0.33%)	1/50 (2%) Mean 4%  0/50 (0%) 0/50 (0%) Mean 0.33%  0/50 (0%)	2/50 (4%) SD 3.35% 1/50 (2%) 0/50 (0%) SD 0.82%
Overall Incidence Lung: Fibrosarcoma Overall Incidence	Total	1/50 (2%) 3/50 (6%) 11/299 (3.68%) 0/50 (0%) 0/50 (0%) 0/299 (0%)	4/50 (8%) 0/50 (0%) Mean 3.68% 0/50 (0%) 0/50 (0%) Mean 0%	1/50 (2%) SD 2.95% 0/49 (0%) 0/50 (0%) SD 0%		4/50 (8%) 12/300 (4%) 0/50 (0%) 0/50 (0%) 1/300 (0.33%)	1/50 (2%) Mean 4%  0/50 (0%) 0/50 (0%) Mean 0.33%	2/50 (4%) SD 3.35% 1/50 (2%) 0/50 (0%) SD 0.82%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

**Page:** 25

Report Date: 05/18/2011

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

			Male				Female	
Lung: Squamous Cell Carcinoma			-1					
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/49 (0%) 0/50 (0%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	1/300 (2%)	0/50 (0%) Mean 0.33%	0/50 (0%) SD 0.82%
		, ,				` ,		
Lymph Node: Hemangiosarcoma								
nemangiosai coma		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Mammary Gland: Adenolipoma								
•		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
Mammary Gland: Adenoma								
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	2/50 (4%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	2/50 (4%)
verall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	4/300 (1.33%)	Mean 1.33%	SD 2.07%
lammary Gland: Carcinoma								
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	4/50 (8%)	1/50 (2%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	6/300 (2%)	Mean 2%	SD 3.1%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: CORN OIL

**Page:** 26

			Male				Female	
#Mammary Gland: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	4/50 (8%)	3/50 (6%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	2/50 (4%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	10/300 (3.33%)	Mean 3.33%	SD 3.27%
#Mammary Gland: Fibroadenoma								
		2/50 (4%)	4/50 (8%)	0/49 (0%)		23/50 (46%)	26/50 (52%)	24/50 (48%)
		0/50 (0%)	0/50 (0%)	1/50 (2%)		17/50 (34%)	29/50 (58%)	21/50 (42%)
Overall Incidence	Total	7/299 (2.34%)	Mean 2.33%	SD 3.2%	Total	140/300 (46.67%)	Mean 46.67%	SD 8.26%
#Mammary Gland: Fibroma								
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Mammary Gland: Fibroma, Fibroadenoma	or Adenoma							
		2/50 (4%)	4/50 (8%)	0/49 (0%)		23/50 (46%)	26/50 (52%)	25/50 (50%)
		0/50 (0%)	0/50 (0%)	1/50 (2%)		17/50 (34%)	29/50 (58%)	22/50 (44%)
Overall Incidence	Total	7/299 (2.34%)	Mean 2.33%	SD 3.2%	Total	142/300 (47.33%)	Mean 47.33%	SD 8.16%
#Mammary Gland: Fibroma, Fibroadenoma,								
•	ŕ	2/50 (4%)	4/50 (8%)	0/49 (0%)		23/50 (46%)	28/50 (56%)	26/50 (52%)
		0/50 (0%)	0/50 (0%)	1/50 (2%)		17/50 (34%)	30/50 (60%)	22/50 (44%)
Overall Incidence	Total	7/299 (2.34%)	Mean 2.33%	SD 3.2%	Total	146/300 (48.67%)	Mean 48.67%	SD 9.35%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

**Toxicology Data Management System** 

Page: 27

Report Date: 05/18/2011

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Male **Female** #Mesentery: **Fibrous Histiocytoma** 0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/300 (0%) **Overall Incidence** Total 0/299 (0%) Mean 0% SD 0% Total Mean 0% SD 0% #Mesentery: Hemangiosarcoma (0%) 0/50 (0%)0/50 0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)Overall Incidence Total 0/299 (0%) Mean 0% SD 0% Total 0/300 (0%) Mean 0% SD 0% #Mesentery: Lipoma 0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/299 (0%) Mean 0% SD 0% Total 0/300 (0%) Mean 0% SD 0% #Mesentery: Schwannoma Malignant 0/49 0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%) 0/50 (0%)0/50 (0%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/299 (0%) Mean 0% SD 0% Total 0/300 (0%) Mean 0% SD 0% \*Nose: Adenoma 0/50 (0%)0/50 (0%)0/49 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/299 (0%) Mean 0% SD 0% Total 0/299 (0%) Mean 0% SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Version: May2011 Contract/Lab: All Laboratories

Species: RATS

Strain: F 344/N

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Page: 28

			Male				Female	
*Nose: Squamous Cell Carcin	oma							
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/299 (0%)	Mean 0%	SD 0%
#Oral Cavity (Oral Mucos Papilloma Squamous o	. •	ynx, Tooth, Gingiva):						
	•	0/50 (0%)	0/50 (0%)	1/49 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	2/299 (0.67%)	Mean 0.67%	SD 1.04%	Total	2/300 (0.67%)	Mean 0.67%	SD 1.03%
Overall Incidence	Total	0/50 (0%) 0/50 (0%) 1/299 (0.33%)	1/50 (2%) 0/50 (0%) Mean 0.33%	0/49 (0%) 0/50 (0%) SD 0.82%	Total	0/50 (0%) 1/50 (2%) 1/300 (0.33%)	0/50 (0%) 0/50 (0%) Mean 0.33%	0/50 (0%) 0/50 (0%) SD 0.82%
#Oral Cavity (Oral Mucos Squamous Cell Carcine	. •	ynx, Tooth, Gingiva): Squamous, or Papilloma						
		0/50 (0%)	1/50 (2%)	1/49 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
O	Taral	1/50 (2%)	0/50 (0%)	0/50 (0%)	T-1-1	2/50 (4%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	3/299 (1%)	Mean 1.01%	SD 1.1%	Total	3/300 (1%)	Mean 1%	SD 1.67%
#Oral Mucosa: Squamous Cell Carcin	oma							
		0/50 (0%)	1/50 (2%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 1/299 (0.33%)	0/50 (0%) Mean 0.33%	0/50 (0%) SD 0.82%	Total	1/50 (2%) 1/300 (0.33%)	0/50 (0%) Mean 0.33%	0/50 (0%) SD 0.82%
	Total	1/299 (0.33%)	iviean 0.33%	SU U.07%	Total	1/300 (0.33%)	iviean 0.33%	SU U.0/%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Version: May2011 Contract/Lab: All Laboratories

Species: RATS

Strain: F 344/N

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Page: 29

			Male				0/50 (0%) 0/50 (0%) 1/50 (2%) 0/50 (0%) Mean 0.33% SD 0.82%  0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) Mean 0.33% SD 0.82%	
Oral Mucosa: Squamous Cell Papillom	a							
		0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)	1/49 (2%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	` ,	` '
Overall Incidence	Total	2/299 (0.67%)	Mean 0.67%	SD 1.04%	Total	0/300 (0%)	` '	` '
Ovary: Cystadenoma								
•						0/50 (0%)	` '	` '
Overall Incidence					Total	0/50 (0%) 1/300 (0.33%)	` '	
Ovary: Fibrosarcoma								
						0/50 (0%)	` ,	` '
Overall Incidence					Total	0/50 (0%) 1/300 (0.33%)	, ,	, ,
Ovary: Granulosa Cell Tumor Be	enign	•••••						
	J					0/50 (0%)	` ,	` '
Overall Incidence					Tatal	1/50 (2%)	` '	` '
					Total	1/300 (0.33%)		SD 0.82%
Ovary: Granulosa Cell Tumor M	alignant							
						0/50 (0%)	` ,	
Overall Incidence					Total	0/50 (0%) 0/300 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Page: 30

Report Date: 05/18/2011

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** \*Ovary: Granulosa Cell Tumor: Benign, Malignant, NOS 0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/300 (0.33%) Mean 0.33% SD 0.82% \*Ovary: **Granulosa-Theca Tumor Benign** 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/300 (0%) Mean 0% SD 0% \*Ovary: **Granulosa-Theca Tumor Malignant** 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/300 (0%) Mean 0% SD 0% \*Ovary: Schwannoma Malignant 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/300 (0%) Mean 0% SD 0% \*Ovary: **Tubulostromal Adenoma** 1/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/300 (0.33%) Mean 0.33% SD 0.82%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: RATS
Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 31 Report Date: 05/18/2011

			Male				Female	
Pancreas: Adenoma								
		0/50 (0%)	7/50 (14%)	1/49 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	0/50 (0%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	11/299 (3.68%)	Mean 3.67%	SD 5.28%	Total	0/300 (0%)	Mean 0%	SD 0%
Pancreas: Carcinoma								
		0/50 (0%)	1/50 (2%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/300 (0%)	Mean 0%	SD 0%
*Pancreas: Carcinoma or Adenoma								
		0/50 (0%)	8/50 (16%)	1/49 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	0/50 (0%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	12/299 (4.01%)	Mean 4.01%	SD 6.06%	Total	0/300 (0%)	Mean 0%	SD 0%
Pancreas: Mixed Tumor Benign								
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
*Pancreas: Mixed Tumor Malignant								
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

**Page:** 32

Report Date: 05/18/2011

Route: GAVAGE

Contract/Lab: All Laboratories

Strain: F 344/N Vehicle: CORN OIL Length of Study: CHRONIC

			Male				Female	
*Parathyroid Gland: Adenoma								
		0/47 (0%)	0/47 (0%)	1/49 (2%)		1/38 (3%)	0/47 (0%)	0/44 (0%)
		1/45 (2%)	0/49 (0%)	1/49 (2%)		0/47 (0%)	0/50 (0%)	2/46 (4%)
Overall Incidence	Total	3/286 (1.05%)	Mean 1.05%	SD 1.15%	Total	3/272 (1.1%)	Mean 1.16%	SD 1.88%
Pituitary Gland: Pars Dis								
		38/50 (76%)	19/50 (38%)	21/49 (43%)		34/50 (68%)	25/50 (50%)	29/50 (58%)
		6/50 (12%)	23/50 (46%)	11/50 (22%)		25/50 (50%)	31/50 (62%)	27/50 (54%)
Overall Incidence	Total	118/299 (39.46%)	Mean 39.48%	SD 22.14%	Total	171/300 (57%)	Mean 57%	SD 7.13%
Carcinoma Overall Incidence	Total	0/50 (0%) 0/50 (0%) 1/299 (0.33%)	0/50 (0%) 1/50 (2%) Mean 0.33%	0/49 (0%) 0/50 (0%) SD 0.82%	Total	2/50 (4%) 0/50 (0%) 3/300 (1%)	0/50 (0%) 0/50 (0%) Mean 1%	1/50 (2%) 0/50 (0%) SD 1.67%
Pituitary Gland: Pars Dis Carcinoma or Adenoma	•	cified Site:						
		38/50 (76%)	19/50 (38%)	21/49 (43%)		36/50 (72%)	25/50 (50%)	30/50 (60%)
		6/50 (12%)	24/50 (48%)	11/50 (22%)		25/50 (50%)	31/50 (62%)	27/50 (54%)
Overall Incidence	Total	119/299 (39.8%)	Mean 39.81%	SD 22.27%	Total	174/300 (58%)	Mean 58%	SD 8.49%
*Pituitary Gland: Pars Dis Ganglioneuroma								
-		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Contract/Lab: All Laboratories

**Toxicology Data Management System** 

**Page:** 33

Report Date: 05/18/2011

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Strain: F 344/N Vehicle: CORN OIL

Length of Study: CHRONIC

Male

			Male				Female	
Pituitary Gland: Pars Interme Adenoma	edia:							
		1/50 (2%)	1/50 (2%)	0/49 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/299 (0.67%)	Mean 0.67%	SD 1.03%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
Pituitary Gland: Pars Interme Carcinoma or Adenoma	edia:							
		1/50 (2%)	1/50 (2%)	0/49 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/299 (0.67%)	Mean 0.67%	SD 1.03%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
*Pituitary Gland: Pars Nervos Craniopharyngioma Overall Incidence		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	0/49 (0%) 0/50 (0%) SD 0%	Total	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) 0/50 (0%) SD 0%
	Total	0/299 (0%)			Total	0/300 (0%)		
Prostate: Adenoma		0/50 (0%)	0/50 (0%)	0/49 (0%)				
Overall Incidence	Total	0/50 (0%) 0/299 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%				
		` '						
Prostate: Carcinoma or Adenoma		0/50 (09/)	0/50 (0%)	0/40 (09/)				
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/49 (0%) 0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%				
		0/299 (0%)						

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
Salivary Glands: Carcinoma								
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/299 (0%)	Mean 0%	SD 0%
Salivary Glands: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/299 (0%)	Mean 0%	SD 0%
Salivary Glands: Sarcoma								
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/299 (0%)	Mean 0%	SD 0%
Salivary Glands: Schwannoma Malignant								
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/299 (0%)	Mean 0%	SD 0%
Seminal Vesicle: Adenoma								
		0/50 (0%)	0/50 (0%)	0/49 (0%)				
		0/50 (0%)	0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%				

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

**Page:** 34

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

**Page:** 35

(0%)

(0%)

Mean 0%

0/50

0/50

SD 0%

(0%)

(0%)

0/50

0/50

Report Date: 05/18/2011

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female #Skeletal Muscle: Fibrous Histiocytoma** 0/50 (0%)0/50 (0%)1/49 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/299 (0.33%) Mean 0.34% SD 0.83% Total 0/300 (0%) Mean 0% SD 0%

#SI	cele	tal	М	us	cle	<b>)</b> :
_						

**Overall Incidence** 

**#Skeletal Muscle:** Hemangiosarcoma

#Skeletal Muscle: Rhabdomyosarcoma								
,,		0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)	0/49 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/300 (0%)	Mean 0%	SD 0%
#Skeletal Muscle:	Dhahdamuam	_						

0/49

0/50

SD 0%

(0%)

(0%)

Total

0/50

0/50

0/300 (0%)

(0%)

(0%)

Rhabdomyosarcoma or Rhabdomyoma

		0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)	0/49 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/300 (0%)	Mean 0%	SD 0%

#### #Skin:

Basal Cell Adenoma

Overall Incidence	Total	4/299 (1.34	l%)	Mean 1.	35%	SD 1.66%	6	Total	1/300 (0.3	33%)	Mean	0.33%	SD 0.	82%
		0/50	(0%)	1/50	(2%)	0/50	(0%)		1/50	(2%)	0/50	(0%)	0/50	(0%)
Basar Gen Adenoma		1/50	(2%)	0/50	(0%)	2/49	(4%)		0/50	(0%)	0/50	(0%)	0/50	(0%)

Total

0/50

0/50

0/299 (0%)

(0%)

(0%)

0/50

0/50

Mean 0%

(0%)

(0%)

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: CORN OIL

**Page:** 36

			Male				Female					
#Skin:												
Basal Cell Adenoma or	r Basosquamou	s Tumor Benign										
		1/50 (2%)	0/50 (0%)	2/49 (4%)		0/50 (0%)	0/50 (0%)	0/50 (0%)				
		0/50 (0%)	1/50 (2%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	4/299 (1.34%)	Mean 1.35%	SD 1.66%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%				
#Skin:												
Basal Cell Adenoma, B	Basosquamous 7	Гumor Benign, or Trichoe	pithelioma									
		1/50 (2%)	0/50 (0%)	2/49 (4%)		0/50 (0%)	0/50 (0%)	0/50 (0%)				
		0/50 (0%)	1/50 (2%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	4/299 (1.34%)	Mean 1.35%	SD 1.66%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%				
#Skin: Basal Cell Carcinoma												
		0/50 (0%)	1/50 (2%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)				
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)				
Overall Incidence	Total	2/299 (0.67%)	Mean 0.67%	SD 1.03%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%				
#Skin:												
Basal Cell Carcinoma	or Basosquamo	us Tumor (malignant or N	•	2/12 (22/)		2/22 (221)	0(=0 (00))	0.750 (00.4)				
		0/50 (0%)	1/50 (2%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)				
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)				
Overall Incidence	Total	2/299 (0.67%)	Mean 0.67%	SD 1.03%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%				
#Skin: Basal Cell Carcinoma, NOS), or Trichoepitheli		noma, Basosquamous Tu	mor (benign, malignaı	nt or								
•		1/50 (2%)	1/50 (2%)	2/49 (4%)		0/50 (0%)	0/50 (0%)	0/50 (0%)				
		1/50 (2%)	1/50 (2%)	0/50 (0%)		1/50 (2%)	1/50 (2%)	0/50 (0%)				
Overall Incidence	Total	6/299 (2.01%)	Mean 2.01%	SD 1.29%	Total	2/300 (0.67%)	Mean 0.67%	SD 1.03%				

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Page: 37 Report Date: 05/18/2011

			Male				Female				
#Skin: Basal or Sq. Cell Carcinoma, Carcinoma, Basosq. Tumor (M or B), Basal Cell Adenoma, Adenoma, Papilloma, Sq Papilloma, Keratoacanthoma, Trichoepithelioma											
		2/50 (4%)	8/50 (16%)	2/49 (4%)		1/50 (2%)	0/50 (0%)	0/50 (0%)			
		3/50 (6%)	4/50 (8%)	3/50 (6%)		1/50 (2%)	2/50 (4%)	1/50 (2%)			
Overall Incidence	Total	22/299 (7.36%)	Mean 7.35%	SD 4.49%	Total	5/300 (1.67%)	Mean 1.67%	SD 1.51%			
#Skin: Fibroma											
		1/50 (2%)	5/50 (10%)	7/49 (14%)		1/50 (2%)	0/50 (0%)	1/50 (2%)			
		3/50 (6%)	6/50 (12%)	3/50 (6%)		2/50 (4%)	1/50 (2%)	3/50 (6%)			
Overall Incidence	Total	25/299 (8.36%)	Mean 8.38%	SD 4.53%	Total	8/300 (2.67%)	Mean 2.67%	SD 2.07%			
#Skin: Fibroma, Fibrosarcom	a, Sarcoma, Myx	xoma, Myxosarcoma, or Fi 2/50 (4%) 4/50 (8%)	brous Histiocytoma 7/50 (14%) 6/50 (12%)	7/49 (14%) 3/50 (6%)		1/50 (2%) 3/50 (6%)	0/50 (0%) 4/50 (8%)	1/50 (2%) 3/50 (6%)			
Overall Incidence	Total	29/299 (9.7%)	Mean 9.71%	SD 4.33%	Total	12/300 (4%)	Mean 4%	SD 3.1%			
#Skin: Fibrosarcoma		0/50 (0%)	1/50 (2%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	3/50 (6%)	0/50 (0%)			
Overall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%	Total	4/300 (1.33%)	Mean 1.33%	SD 2.42%			
#Skin:		a, or Fibrous Histiocytoma									
·		1/50 (2%)	2/50 (4%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
		1/50 (2%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	3/50 (6%)	0/50 (0%)			
Overall Incidence	Total	4/299 (1.34%)	Mean 1.33%	SD 1.63%	Total	4/300 (1.33%)	Mean 1.33%	SD 2.42%			

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Page: 38

Report Date: 05/18/2011

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #Skin: **Fibrous Histiocytoma** 1/50 (2%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/300 (0%) **Overall Incidence** Total 1/299 (0.33%) Mean 0.33% SD 0.82% Total Mean 0% SD 0% #Skin: Hemangioma 0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/299 (0%) Mean 0% SD 0% Total 0/300 (0%) Mean 0% SD 0% #Skin: Hemangiosarcoma 0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/299 (0%) Mean 0% SD 0% 0/300 (0%) Mean 0% SD 0% Total #Skin:

0/49

3/50

SD 4.63%

1/49

0/50

SD 1.68%

(0%)

(6%)

(2%)

(0%)

Total

Total

0/50

0/50

0/50

0/50

0/300 (0%)

1/300 (0.33%)

(0%)

(0%)

(0%)

(0%)

0/50

1/50

0/50

0/50

(0%)

(2%)

(0%)

(0%)

Mean 0.33%

Mean 0%

0/50

0/50

0/50

0/50

SD 0.82%

SD 0%

(0%)

(0%)

(0%)

(0%)

Total

Total

2/50

2/50

17/299 (5.69%)

0/50

0/50

3/299 (1%)

(4%)

(4%)

(0%)

(0%)

.....

7/50

3/50

2/50

0/50

Mean 1.01%

Mean 5.67%

(14%)

(6%)

(4%)

(0%)

Keratoacanthoma

**Overall Incidence** 

**Overall Incidence** 

#Skin: Lipoma

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Page: 39

(0%)

(0%)

(0%)

(0%)

Mean 0%

Mean 0%

0/50

0/50

0/50

0/50

SD 0%

SD 0%

(0%)

(0%)

(0%)

(0%)

0/50

0/50

0/50

0/50

Report Date: 05/18/2011

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #Skin: Liposarcoma 0/50 (0%)0/50 (0%)1/49 (2%)0/50 (0%)0/50 (0%)0/50 (0%)(0%) 0/50 (0%)0/50 (0%)0/50 0/50 (0%)1/50 (2%)0/50 (0%)1/300 (0.33%) **Overall Incidence** Total 1/299 (0.33%) Mean 0.34% SD 0.83% Total Mean 0.33% SD 0.82% #Skin: **Neural Crest Tumor** (0%)(0%)0/50 0/50 (0%)0/49 (0%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)Overall Incidence Total 0/299 (0%) Mean 0% SD 0% Total 0/300 (0%) Mean 0% SD 0% #Skin: **Neural Crest Tumor, Malignant** 0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/299 (0%) Mean 0% SD 0% 0/300 (0%) Mean 0% SD 0% Total #Skin:

0/49

0/50

SD 0%

0/49

3/50

SD 2.42%

(0%)

(0%)

(0%)

(6%)

Total

Total

0/50

0/50

0/50

0/50

0/300 (0%)

0/300 (0%)

(0%)

(0%)

(0%)

(0%)

Neurofibrosarcoma or Schwannoma (malignant or NOS)

Total

Total

0/50

0/50

0/299 (0%)

0/50

4/299 (1.34%)

(0%)

(0%)

(2%)

(0%)

0/50

0/50

0/50

0/50

Mean 1.33%

Mean 0%

(0%)

(0%)

(0%)

(0%)

Neurofibroma or Schwannoma benign

**Overall Incidence** 

**Overall Incidence** 

#Skin:

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Version: May2011 Contract/Lab: All Laboratories

Species: RATS

Strain: F 344/N

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

**Page:** 40

Report Date: 05/18/2011

			Male				Female	
#Skin: Neurofibrosarcoma, Neuro	fibroma, or	Schwannoma (benign, m	alignant or NOS)					
		1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/49 (0%) 3/50 (6%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	4/299 (1.34%)	Mean 1.33%	SD 2.42%	Total	0/300 (0%)	Mean 0%	SD 0%
#Skin: Sarcoma								
		0/50 (0%)	1/50 (2%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/50 (2%) 2/299 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.03%	Total	0/50 (0%) 0/300 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
	• • • • • • • • • • • • • • • • • • • •		•••••					
#Skin: Schwannoma Benign								
•		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Skin: Schwannoma Malignant								
		1/50 (2%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 4/299 (1.34%)	0/50 (0%) Mean 1.33%	3/50 (6%) SD 2.42%	Total	0/50 (0%) 0/300 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Skin: Squamous Cell Carcinoma		2(72 (224)	2/22 (22()	0 (10 (100))		477	0(70 (00))	2/22 (221)
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/49 (0%) 0/50 (0%)		1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

Page: 41

Mean 0.67%

SD 1.03%

Report Date: 05/18/2011

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #Skin: Squamous Cell Carcinoma, Basal Cell Carcinoma, Basosquamous Tumor (malignant or NOS), or Carcinoma 0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)(2%)0/49 (0%)1/50 1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)**Overall Incidence** Total 2/299 (0.67%) Mean 0.67% SD 1.03% Total 2/300 (0.67%) Mean 0.67% SD 1.03% #Skin: **Squamous Cell Papilloma** 0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%) 0/50 (0%)0/50 (0%)1/50 (2%)0/299 (0%) Mean 0% SD 0% 1/300 (0.33%) Mean 0.33% SD 0.82% **Overall Incidence** Total Total #Skin: Squamous Cell Papilloma or Papilloma 0/50 0/50 (0%)0/50 0/50 0/50 (0%)0/49 (0%)(0%)(0%)(0%)(0%) 0/50 (0%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)**Overall Incidence** Total 0/299 (0%) Mean 0% SD 0% Total 1/300 (0.33%) Mean 0.33% SD 0.82% #Skin: Squamous Cell Papilloma, Papilloma, Squamous Cell Carcinoma or Keratoacanthoma 2/50 (4%)7/50 (14%)0/49 (0%)1/50 (2%)0/50 (0%)0/50 (0%)(4%)2/50 3/50 (6%)3/50 (6%)0/50 (0%)1/50 (2%)1/50 (2%)Mean 5.67% **Overall Incidence** Total 17/299 (5.69%) SD 4.63% Total 3/300 (1%) Mean 1% SD 1.1% #Skin: Squamous Cell Papilloma, Papilloma, or Keratoacanthoma (4%)7/50 (14%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)2/50 (4%)3/50 (6%)3/50 (6%)0/50 (0%)1/50 (2%)1/50 (2%)

SD 4.63%

Total

2/300 (0.67%)

Total

17/299 (5.69%)

Mean 5.67%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Page: 42

Mean 0%

SD 0%

Report Date: 05/18/2011

Contract/Lab: All Laboratories

Species: RATS Strain: F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Male **Female** #Skin: Trichoepithelioma 0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/300 (0%) **Overall Incidence** Total 0/299 (0%) Mean 0% SD 0% Total Mean 0% SD 0% #Skin: Sebaceous Gland: Adenoma (0%)0/50 (0%)1/50 (2%)0/49 (0%)0/50 0/50 (0%)0/50 (0%)1/50 (2%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)Mean 0% **Overall Incidence** Total 3/299 (1%) Mean 1% SD 1.1% Total 0/300 (0%) SD 0% **#Skin: Sebaceous Gland:** Carcinoma or Adenoma 0/50 (0%)1/50 (2%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 3/299 (1%) Mean 1% SD 1.1% Total 0/300 (0%) Mean 0% SD 0% **#Spinal Cord:** Astrocytoma Benign 0/49 0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/299 (0%) Mean 0% SD 0% Total 1/300 (0.33%) Mean 0.33% SD 0.82% **#Spinal Cord: Astrocytoma Malignant** 0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)

SD 0%

Total

0/300 (0%)

Total

0/299 (0%)

Mean 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Page: 43

Report Date: 05/18/2011

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female #Spinal Cord: Glioma Malignant** 0/50 (0%)0/50 (0%)1/49 (2%)0/50 (0%)0/50 (0%)0/50 (0%)(0%) 0/50 (0%)0/50 (0%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/300 (0%) **Overall Incidence** Total 1/299 (0.33%) Mean 0.34% SD 0.83% Total Mean 0% SD 0% \*Spleen: **Fibrosarcoma** (0%) 0/50 (0%)0/50 0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)Mean 0% **Overall Incidence** Total 0/299 (0%) SD 0% Total 0/300 (0%) Mean 0% SD 0% \*Spleen: Fibrous Histiocytoma 0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/299 (0%) Mean 0% SD 0% Total 0/300 (0%) Mean 0% SD 0% \*Spleen: Hemangiosarcoma 0/49 0/50 (0%)1/50 (2%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)2/50 (4%)**Overall Incidence** Total 1/299 (0.33%) Mean 0.33% SD 0.82% Total 2/300 (0.67%) Mean 0.67% SD 1.63% \*Spleen: Leiomyosarcoma 0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/299 (0%) Mean 0% SD 0% Total 0/300 (0%) Mean 0% SD 0%

......

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

**Toxicology Data Management System** 

Page: 44

Report Date: 05/18/2011

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

			Male				Female	
Spleen: Sarcoma								
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: Leiomyosarcoma								
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: Squamous Cell Carcinom	a							
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: Squamous Cell Carcinom	a or Papilloma	a Squamous						
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
#Stomach, Forestomach: Squamous Cell Papilloma	ı							
-		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
Stomach, Glandular: Carcinoma								
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Stomach, Glandular: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Stomach, Glandular: Lipoma								
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Stomach, Glandular: Sarcoma								
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
Testes: Adenoma								
		37/50 (74%)	46/50 (92%)	37/49 (76%)				
		47/50 (94%)	40/50 (80%)	46/50 (92%)				
Overall Incidence	Total	253/299 (84.62%)	Mean 84.59%	SD 9.1%				

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

**Page:** 45

Report Date: 05/18/2011

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

**Page:** 46

Mean 0.33%

SD 0.82%

Report Date: 05/18/2011

Contract/Lab: All Laboratories

**Species:** RATS **Strain:** F 344/N

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

			Male				Female	
Testes: Hemangioma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	0/49 (0%) 0/50 (0%)				
Overall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%				
Thymus: Thymoma Benign								
,		1/47 (2%)	0/47 (0%)	0/48 (0%)		1/50 (2%)	0/47 (0%)	0/50 (0%)
		0/47 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/47 (0%)	0/50 (0%)
Overall Incidence	Total	1/289 (0.35%)	Mean 0.35%	SD 0.87%	Total	1/293 (0.34%)	Mean 0.33%	SD 0.82%
Thymus: Thymoma Malignant								
		0/47 (0%)	0/47 (0%)	0/48 (0%)		0/50 (0%)	0/47 (0%)	0/50 (0%)
		0/47 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/47 (0%)	0/50 (0%)
Overall Incidence	Total	0/289 (0%)	Mean 0%	SD 0%	Total	0/293 (0%)	Mean 0%	SD 0%
Thymus: Thymoma NOS								
		0/47 (0%)	0/47 (0%)	0/48 (0%)		0/50 (0%)	0/47 (0%)	0/50 (0%)
		0/47 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/47 (0%)	0/50 (0%)
Overall Incidence	Total	0/289 (0%)	Mean 0%	SD 0%	Total	0/293 (0%)	Mean 0%	SD 0%
Thymus: Thymoma: Benign, Malig	nant, NOS							
	·	1/47 (2%)	0/47 (0%)	0/48 (0%)		1/50 (2%)	0/47 (0%)	0/50 (0%)
		0/47 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/47 (0%)	0/50 (0%)

SD 0.87%

Total

1/293 (0.34%)

Mean 0.35%

Total

1/289 (0.35%)

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Report Date: 05/18/2011

Page: 47

Mean 0.33%

SD 0.82%

			Male				Female	
Thyroid Gland: C-Cell: Adenoma								
		10/50 (20%)	9/50 (18%)	8/49 (16%)		11/49 (22%)	7/50 (14%)	5/50 (10%)
wanali laasalaanaa	Tatal	12/50 (24%)	11/50 (22%)	8/50 (16%)	Tatal	5/50 (10%)	9/49 (18%)	8/50 (16%)
verall Incidence	Total	58/299 (19.4%)	Mean 19.39%	SD 3.2%	Total	45/298 (15.1%)	Mean 15.14%	SD 4.87%
Thyroid Gland: C-Cell: Carcinoma								
		1/50 (2%)	6/50 (12%)	0/49 (0%)		0/49 (0%)	3/50 (6%)	0/50 (0%)
	<b>-</b>	0/50 (0%)	0/50 (0%)	0/50 (0%)	<b>+</b>	0/50 (0%)	0/49 (0%)	0/50 (0%)
verall Incidence	Total	7/299 (2.34%)	Mean 2.33%	SD 4.8%	Total	3/298 (1.01%)	Mean 1%	SD 2.45%
Thyroid Gland: C-Cell: Carcinoma or Adenoma								
		11/50 (22%)	15/50 (30%)	8/49 (16%)		11/49 (22%)	9/50 (18%)	5/50 (10%)
		12/50 (24%)	11/50 (22%)	8/50 (16%)		5/50 (10%)	9/49 (18%)	8/50 (16%)
verall Incidence	Total	65/299 (21.74%)	Mean 21.72%	SD 5.21%	Total	47/298 (15.77%)	Mean 15.8%	SD 4.96%
Γhyroid Gland: Follicular Adenoma								
		2/50 (4%)	1/50 (2%)	1/49 (2%)		1/49 (2%)	0/50 (0%)	1/50 (2%)
		1/50 (2%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	1/49 (2%)	0/50 (0%)
verall Incidence	Total	6/299 (2.01%)	Mean 2.01%	SD 1.27%	Total	3/298 (1.01%)	Mean 1.01%	SD 1.11%
Γhyroid Gland: Follicular Carcinoma								
		0/50 (0%)	1/50 (2%)	0/49 (0%)		0/49 (0%)	1/50 (2%)	0/50 (0%)
		2/50 (4%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)

SD 1.67%

Total

1/298 (0.34%)

Total

3/299 (1%)

Mean 1%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS Strain: F 344/N

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

**Page:** 48

Report Date: 05/18/2011

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
*Thyroid Gland: Follicular Cel Carcinoma or Adenoma	l:							
		2/50 (4%)	2/50 (4%)	1/49 (2%)		1/49 (2%)	1/50 (2%)	1/50 (2%)
		3/50 (6%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	1/49 (2%)	0/50 (0%)
Overall Incidence	Total	9/299 (3.01%)	Mean 3.01%	SD 2.09%	Total	4/298 (1.34%)	Mean 1.35%	SD 1.04%
†Tissue NOS: Paraganglioma								
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Tongue: Squamous Cell Carcinoma								
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Tongue: Squamous Cell Carcinoma	or Papillom	na Squamous						
1		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	1/50 (2%)	0/50 (0%)
verall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	2/300 (0.67%)	Mean 0.67%	SD 1.03%
Tongue: Squamous Cell Papilloma								
-		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	2/300 (0.67%)	Mean 0.67%	SD 1.03%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

**Toxicology Data Management System** 

**Page:** 49

Report Date: 05/18/2011

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

			Male				Female	
#Tooth: Adamantinoma Malignant								
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Tooth: Odontoma								
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
Urinary Bladder: Carcinoma								
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Urinary Bladder: Carcinoma or Papilloma								
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
Urinary Bladder: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

**Page:** 50

Report Date: 05/18/2011

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** \*Urinary Bladder: **Papilloma** 0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)**Overall Incidence** Total 1/299 (0.33%) Mean 0.33% SD 0.82% Total 1/300 (0.33%) Mean 0.33% SD 0.82% #Uterus: Adenoma 0/50 (0%) 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/300 (0%) Mean 0% SD 0% #Uterus: Carcinoma 0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/300 (0.33%) Mean 0.33% SD 0.82% #Uterus: Deciduoma Benign 0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/300 (0.33%) Mean 0.33% SD 0.82% **#Uterus:** Leiomyosarcoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/300 (0%) Mean 0% SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

**Page:** 51

Report Date: 05/18/2011

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

	Male			Female	
#Uterus: Polyp Stromal					
Polyp Stromai			3/50 (6%)	8/50 (16%)	7/50 (14%)
			8/50 (16%)	3/50 (6%)	5/50 (10%)
Overall Incidence		Total	34/300 (11.33%)	Mean 11.33%	SD 4.68%
#Uterus: Sarcoma					
			0/50 (0%)	0/50 (0%)	0/50 (0%)
			0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence		Total	0/300 (0%)	Mean 0%	SD 0%
#Uterus: Sarcoma Stromal					
			0/50 (0%)	0/50 (0%)	1/50 (2%)
			0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence		Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
#Uterus: Sarcoma Stromal or Polyp Stromal					
			3/50 (6%)	8/50 (16%)	7/50 (14%)
			8/50 (16%)	3/50 (6%)	5/50 (10%)
Overall Incidence		Total	34/300 (11.33%)	Mean 11.33%	SD 4.68%
#Uterus: Schwannoma Malignant					
-			1/50 (2%)	0/50 (0%)	0/50 (0%)
			0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence		Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Page: 52

Report Date: 05/18/2011

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #Vagina: Polyp 0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/300 (0.33%) Mean 0.33% SD 0.82% #Vagina: Sarcoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/300 (0%) Mean 0% SD 0% #Vagina: Schwannoma Malignant 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)**Overall Incidence** Total 1/300 (0.33%) Mean 0.33% SD 0.82% #Zymbal's Gland: Adenoma 0/49 0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%) 0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/299 (0%) Mean 0% SD 0% Total 0/300 (0%) Mean 0% SD 0% #Zymbal's Gland: Carcinoma 1/50 (2%)2/50 (4%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)**Overall Incidence** Total 3/299 (1%) Mean 1% SD 1.67% Total 1/300 (0.33%) Mean 0.33% SD 0.82%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: RATS

Strain: F 344/N

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Female

**Page:** 53

Report Date: 05/18/2011

			Male		Female	
#Zymbal's Gland: Carcinoma or Adenoma						
		1/50 (2%)	2/50 (4%) 0/49 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)	
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%) 1/50 (2%)	
Overall Incidence	Total	3/299 (1%)	Mean 1% SD 1.67%	Total 1/300 (0.33%)	Mean 0.33% SD 0.82%	

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied